POSTER SESSION II:
DISEASE-SPECIFIC STUDIES

Diabetes/Endocrine Disorders – Clinical Outcomes Studies

PDB1
TREATMENT PATTERNS AND OUTCOMES AMONG OLDER EXENATIDE BID USERS COMPARED TO INSULIN GLARGINE USERS

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OBJECTIVES: We evaluated treatment patterns, hypoglycemic events, glycemic control and medical costs for patients >60y with type 2 diabetes mellitus (T2DM) newly initiating treatment on exenatide BID (ExBID) or insulin glargine (IG). **METHODS:** Medical, pharmacy and lab data for commercial and Medicare Advantage enrollees were obtained from administrative claims from a large, national health plan. Subjects were identified from May 2005 to Dec 2008 with 6-mo baseline and 12-mo follow-up periods. Subjects with any insulin treatment during baseline were excluded. Propensity score (PS) matching (1:1) of ExBID and IG subjects was used to create balanced cohorts. Logistic regression models were used to analyze medication adherence (Medication Possession Ratio (MPR) >=80%), therapy persistence (gap of 60 days in treatment = discontinuation), any acute hypoglycemic event, and glycemic control (follow-up A1C levels of <7%). **RESULTS:** The final matched study sample included 3,263 subjects per cohort; average age was 65y (SD 4.9); 48% were female; 83% were enrolled in a commercial health plan. In the follow-up period, ExBID patients experienced significantly fewer hypoglycemic events compared to IG patients (15 vs. 40, p<0.001). Subjects in the ExBID cohort were also more likely to obtain an MPR>=80% (Odds Ratio (OR) =1.93, CL 1.72-2.17), less likely to discontinue therapy (OR=0.28, CL 0.25-0.31) and less likely to have any acute hypoglycemic event (OR=0.48, CL 0.26-0.88) during the follow-up period. For those with valid A1C levels in both baseline and follow-up periods (N=669; ExBID=359, IG=310), ExBID subjects were more likely to achieve A1C <7% (OR=1.62, CL 1.11-2.35) compared to IG subjects. Associated medical costs were similar for both groups. Results were comparable for patients > 65y. **CONCLUSIONS:** Older ExBID subjects were more likely to adhere to therapy and achieve A1C <7% and less likely to discontinue therapy or experience any acute hypoglycemic event than older IG subjects.

PDB2
EVALUATING ONE-YEAR STABILITY OF THE TOTAL ILLNESS BURDEN INDEX

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OBJECTIVES: The Total Illness Burden Index (TIBI) is a well-validated, patient-reported measure of the presence and severity of medical conditions comorbid to an index condition and is an important component of the Potential for Benefit Conceptual Model, shown to predict response to treatment in diabetes. The objective of this research was to determine the one-year stability of the TIBI. **METHODS:** We identified patients with type 2 diabetes enrolled in the Reducing Racial Disparities in Diabetes Coached Care (R2D2C2) study who had completed the 47-item TIBI at baseline and one year follow-up, and whose antihyperglycemic medication regimen had not changed (n=364). For this sample, we estimated standard error of measurement (SEM) for the TIBI and compared changes in TIBI scores using paired t-tests and limits of agreement. **RESULTS:** SEM for the TIBI-47 was 0.90. Scores for baseline and follow-up were 3.52 and 2.88 respectively (range = 0-13), mean improvement = 0.64, within the SEM. 82.2% of respondents had a change in the TIBI score of ≤3 points. Minor improvements (≤ 5% of scale range) were observed in transient symptoms (e.g. flu with cough, shortness of breath, etc.) versus diagnoses (e.g. congestive heart failure, stroke, etc.). All changes in symptoms were within SEM for respective TIBI subdimensions. **CONCLUSIONS:** TIBI scores appeared to be highly stable for this study sample over the one-year observation period. Small changes observed in symptom severity items may be due to effective clinical management. Further research is needed to distinguish observed differences due to treatment response from measurement error.

PDB3
LONG-TERM ANTIPROTEINURIC EFFECT OF ALISKIREN IN DIABETIC PATIENTS WITH PERSISTENT ALBUMINURIA DESPITE CHRONIC ACEI OR ARB TREATMENT

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OBJECTIVES: Studies showed dual blockade of renin-angiotensin-aldosterone system with ACEI and ARB had produced little gain with significant side effects in proteinuric patients. Here we evaluated the real-world effectiveness of long-term antiproteinuric effects of a novel dual blockade with the direct renin inhibitor aliskiren addition on chronic ACEI or ARB treatment in diabetic patients with persistent albuminuria. **METHODS:** We retrospectively collected data from the electronic database of Baywest Endocrinology Associates. Aliskiren150- 300mg daily was added on chronic ACEI/ARB treatment (mean known duration 6 years). The Cockroft-Gault formula was used to estimate the glomerular filtration rate (eGFR). The Wilcoxon Signed Ranks test and Kendall's tau-b correlation analysis were used to calculate statistical significance. $p<0.05$ was considered significant. **RESULTS:** Twenty-four (mean age 64 years) patients were selected, with a mean observation time 15 months before and 20 months after aliskiren addition. There was a significant rise in urinary albumin-to-creatinine ratio (Ualb/Cr) [unit: mg/g, 146.3 (16.1-1978.7) vs. 51.0 (34-1170.3)] and SBP (unit: mmHg, 158 ± 19 vs. 142± 21) in these patients at baseline (i.e., when Aliskiren was added) when compared with that of 15 months before ($p<0.05$). And there was a significant decline in albuminuria and SBP 20 months after aliskiren addition: reduced median Ualb/Cr was 73.3%, reduced mean SBP was 24 mmHg ($p=0.001$). However, reduction in Ualb/Cr was not related to reduction in SBP ($p>0.05$). No changes were found in the DBP, HbA1c, serum creatinine and eGFR. A small increment of serum potassium levels was detected after aliskiren addition(unit: mmol/L, 4.5±0.6 vs 4.4 ± 0.4 mmol/L at baseline, $p<0.05$). During the study, no adverse events, including symptoms of hyperkalemia and hypotension, were documented. **CONCLUSIONS:** Aliskiren addition to ACEI/ARB may have extra antiproteinuric effects that might be independent on BP reduction and held without rebound as long as 1.5 year follow-up.

PDB4
MODELING HEALTH AND ECONOMIC OUTCOMES ASSOCIATED WITH EXENATIDE ONCE-WEEKLY VERSUS INSULIN AND PIOGLITAZONE TREATMENT FOR TYPE-2 DIABETES

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OBJECTIVES: Exenatide once-weekly (ExQW) is a GLP-1 receptor agonist that improves glycemia in patients with type 2 diabetes (T2DM) while eliciting potential weight loss and improvement in cardiovascular risk factors (blood pressure (BP) and plasma lipids). In published trials, ExQW resulted in superior reduction in A1C compared to maximum daily doses of sitagliptin and pioglitazone (Pio) on metformin (Met) background, and to titrated insulin glargine. **METHODS:** We used the Archimedes Model, a validated, clinically detailed model of physiology, disease, and healthcare delivery, to explore potential long-term ExQW benefits and costs. We simulated 20y of treatment in a virtual population (n=19,885) based on individuals with T2DM drawn from NHANES who were on Met+/−sulfonylureas (mean age 59y, BMI 33kg/m^2, wt 93kg, duration T2DM 9y, baseline A1C 8%). The effects of three treatment regimens were modeled at simulation start: 1) advancement to insulin at A1C ≥8% (treat to target A1C<7%), 2) addition of Pio, and 3) addition of ExQW. ExQW's effect on A1C, weight, BP, and lipids was derived from four phase 3 ExQW trials. Medical costs (inpatient, outpatient, ambulatory, treatments) were derived from the Medicare Current Beneficiary Survey, Medicare Part D data, drugstore.com, and published literature. Since ExQW is investigational, antidiabetic therapy costs were excluded. **RESULTS:** At 20y, final mean A1C was ~7% in all arms. Compared to insulin and Pio, respectively, ExQW was associated with relative reductions in final mean weight (5% vs. both comparators), incidence of first Major Adverse Cardiovascular Event (8.2% and 3.3%), and CHF (5.1% and 15.0%). All arms showed comparable benefit in controlling neuropathy, but ExQW showed significantly greater reductions in renal complications. As early as 5y, ExQW demonstrated total cost-savings of $545 and $379 per life-year vs. insulin and Pio, respectively. **CONCLUSIONS:** These simulations suggest that the benefits of ExQW may translate into clinically and economically meaningful reductions in long-term outcomes.

PDB5
THE IMPACT OF ANTIDIABETIC-INDUCED HYPOGLYCEMIA ON CLINICAL OUTCOMES AND RESOURCE UTILIZATION AMONG VETERANS WITH TYPE-2 DIABETES MELLITUS (T2DM)

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OBJECTIVES: To examine the impact of antidiabetic-induced hypoglycemia on clinical outcomes and resource utilization among T2DM patients in the Veterans Affairs. **METHODS:** This retrospective cohort study used electronic medical records between 01/01/2004 and 09/01/2010 from the Veterans Integrated Service Network (VISN) 16 data warehouse. Patients were required to have at least 2 records of T2DM ICD-9-CM diagnosis (250.xx except for 250.x1 and 250.x3). The first dispense date of a new antidibetic agent (index drug) were defined as the index date. No hypoglycemia diagnosis was allowed during the one-year pre-index period. The hypoglycemia cohort and control cohort were defined by ICD-9-CM diagnosis of hypoglycemia (250.8, 251.0, 251.1 and 251.2) within the index-treatment period and no hypoglycemia during the one-year post-index period, respectively. Clinical outcomes included hemoglobin A1c, cardiovascular diseases (CVD) and micro-vascular complications. Resource utilization included hospitalizations and emergency room (ER) visits. Clinical outcomes were compared by Cox regression models, controlling for age, race, index drug, renal functions, and baseline variables: A1c, Charlson comorbidity index (CCI), and resource utilization. **RESULTS:** Among 42,437 T2DM patients, 369 patients of the hypoglycemia cohort and 42,068 patients of the control cohort differed in racial and marital status, baseline CCI and resource utilization. The hypoglycemia cohort was more likely to receive insulin/sulfonylurea as index drug. The post-index A1c was numerically higher in the hypoglycemia cohort than control cohort (10.12 vs 9.87, p = 0.0602). The hypoglycemia cohort was more likely to develop CVD (HR=1.32, 95%CI: 1.13-1.54) and 40% more likely to develop micro-vascular complications, compared with the control cohort. Risks of hospitalization and ER visit were higher for the hypoglycemia cohort than control cohort (18.2% vs. 9.2%, 32.3% vs. 20.7%, both p-values < .0001, respectively). **CONCLUSIONS:** Patients with hypoglycemia may lead to worse clinical outcomes and higher risks of hospitalization and ER visit than those without.

PDB6
LONG-TERM EFFECTIVENESS OF MANAGING DIABETES WITH THE CHRONIC CARE MODEL: SIMULATIONS PERFORMED USING ARCHES

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